DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 30, 2014

KJ Meditech Co., Ltd.
c/o Priscilla Juhee Chung
LK Consulting Group USA, Inc.
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

Re: K140051
Trade/Device Name: KJ External Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 23, 2014
Received: September 29, 2014

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)* K140051

Device Name
KJ External Implant System

Indications for Use *(Describe)*
KJ External Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. KJ External Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

# 510(k) Summary

(K140051)

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 10/29/2014

## 1. Applicant / Submitter

KJ Meditech Co., Ltd.
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## 2. US Agent / Submission Contact Person

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Priscilla Juhee Chung
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Email: juhee.c@lkconsultinggroup.com

## 3. Device

- Trade Name: KJ External Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant System
- Product Code: DZE, NHA
- Classification regulation: 21CFR872.3640

## 4. Predicate Device:

US SYSTEM by Osstem Implant Co., Ltd. (K062030)
Hero II Dental Implant System, IS Dental Implant System by KJ Meditech Co., Ltd. (K121047)

## 5. Description:

The KJ External Implant System is a dental implant system made of Titanium 6AL 4V ELI alloy intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period.
The implants may be used to replace one or more missing teeth. The system is similar to other commercially available products based on the intended use, the technology used, the

claims, the material composition employed and performance characteristics. The surface of the implants has been treated with R.B.M (Resorbable Blast Media).
The KJ External Implant is offered in the following sizes.

| Material: Ti 6Al 4V ELI, ASTM F136 | |
|---|---|
| Dia.(mm) | Length(mm) |
| ⌀3.3 | 8.0 |
| | 10.0 |
| | 11.5 |
| | 13.0 |
| | 16.0 |
| | 18.0 |
| ⌀3.8 | 8.0 |
| | 10.0 |
| | 11.5 |
| | 13.0 |
| | 16.0 |
| | 18.0 |
| ⌀4.0 | 8.0 |
| | 10.0 |
| | 11.5 |
| | 13.0 |
| | 16.0 |
| | 18.0 |
| ⌀4.5 | 8.0 |
| | 10.0 |
| | 11.5 |
| | 13.0 |
| | 16.0 |
| | 18.0 |
| ⌀5.0 | 8.0 |
| | 10.0 |
| | 11.5 |
| | 13.0 |
| | 16.0 |
| | 18.0 |
| ⌀5.1 | 8.0 |
| | 10.0 |
| | 11.5 |
| | 13.0 |
| | 16.0 |
| ⌀6.0 | 8.0 |
| | 10.0 |
| | 11.5 |
| | 13.0 |

## 6. Indication for use:

The KJ External Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. KJ External Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

## 7. Basis for Substantial Equivalence

Similarities

The KJ External Implant System has the same intended use as the identified predicate device (K062030). The KJ External Implant System and US System are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with RBM roughened surfaces. They all share same external hexagon abutment connection system with external beveled interface for maximum prosthetic stability. The subject and predicate devices are both bone-level implants that share similar neck design and cutting edge.

Difference

The difference is the body shape; the subject device has straight body, whereas the predicate device (K062030) has semi-tapered shape. However this is only the minor design factor, so it does not raise new questions on safety and effectiveness of the subject device.

## 8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137, ISO 11737-1 & ISO 11737-2 for gamma sterilization and ISO 17665-1 and ISO 17665-2 for steam sterilization.
- Three year of shelf life has been validated through accelerating testing.
- Chemical and SEM image analyses have been performed to verify that there is no residual after RBM treatment on the fixtures.

## 9. Conclusion

The subject devices and the predicate devices have the same intended use and have similar technological characteristics. The subject and predicate implants are all made of commercially pure titanium and have the same surface treatments.

Overall, the KJ External Implant System has the following similarities to the predicate devices:

* has the same intended use,
* uses the same operating principle,
* incorporates the same basic design,
* incorporates the same material and the surface treatment.

Based on the similarities, we conclude that the KJ External Implant System is substantially equivalent to the predicate device.